

### **REMARKS**

Claims 16-17 and 19-33 are pending and stand rejected. Applicant has reviewed the Office action, including the Examiner's remarks and the references cited therein. Applicant submits that the following remarks are fully responsive to the Office action, and that all pending claims are patentable over the cited references.

#### **Double Patenting Rejection**

The Examiner rejects claims 16-17 and 19-33<sup>1</sup> on the grounds of nonstatutory, obviousness-type double patenting over claims 1 and 7 of United States patent no. 7,234,225. The Examiner also provisionally rejects claims 16-17 and 19-33 on the grounds of nonstatutory, obviousness-type double patenting over claims 1-18 of United States application no. 11/819,297.

Applicant will submit appropriate terminal disclaimers to overcome the double patenting rejections upon receiving an indication of allowable subject matter.

#### **Rejection Under 35 U.S.C. § 102**

The Examiner rejects claims 16, 17, 19, 21-23, 25-27, and 29-33 under 35 U.S.C. § 102(b) as anticipated by United States patent no. 5,417,208 to Winkler ("Winkler"). To be anticipatory, a single prior art reference must explicitly or inherently teach each and every element of the claimed invention. MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Applicant respectfully submits that Winkler fails to meet this standard.

Claim 33 recites, *inter alia*, "at least one arbitrarily-shaped electrode overmolded by a portion of the catheter, at least a portion of the at least one arbitrarily-shaped electrode being exposed through and completely surrounded by the overmold of the catheter[.]" By way of further explanation, in some embodiments of the invention, because the arbitrarily-shaped electrode is "exposed through and completely

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<sup>1</sup> The Office action indicates that claims 16-33 are rejected. In view of the previous cancellation of claim 18, Applicant believes that this is a correct statement of the rejection.

surrounded by the overmold of the catheter,” the arbitrarily-shaped electrode is disposed on an exterior surface of the catheter (e.g., flush with the catheter’s outer surface). Specification, paras. [0039], [00147].

Winkler, on the other hand, teaches a conductive core 42 having an insulating layer 44 about which conductive wires 45 are wound. An insulating layer is formed over the core-covering layer 44 and the exposed portion of wires 45, thereby forming a hard outer layer 20 defining an outer surface 21. Winkler, col. 4:60-5:47. At this stage of the manufacture of the device according to Winkler, there is no “portion of the at least one arbitrarily-shaped electrode ... exposed through and completely surrounded by the overmold of the catheter” as recited in claim 33.

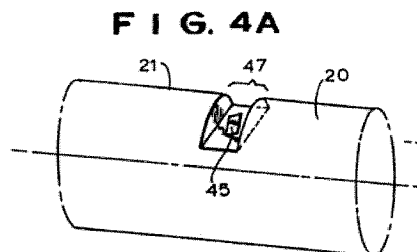
Next, the hard layer 20 is removed to form windows 47 that expose portions of wires 45. *Id.*, col. 6:6-12. Winkler then teaches that electrodes 30 are crimped to make contact with the wires 45, leaving an electrode that is neither “exposed through” nor “completely surrounded by” overmold material, but rather an electrode that is wrapped around the overmold material. *Id.*, col. 7:23-64. Thus, it is only at an intermediate stage of the manufacture of the Winkler device that an electrically conductive element is “exposed through and completely surrounded by” overmold, and this electrically conductive element is not on the exterior surface of the catheter as in the present invention.

Applicant further respectfully disagrees with the Examiner’s apparent characterization of the exposed wires 45 of Winkler as the claimed arbitrarily-shaped electrodes “exposed through and completely surrounded by the overmold of the catheter ... .” Indeed, Winkler expressly states that “[e]lectrically conductive wires *have never proven to be entirely satisfactory as the electrodes* since a functional electrode *requires a much larger surface area than can be provided by a flexible wire.*” *Id.*, col. 1:32-35 (emphasis added). Thus, Winkler’s wires 45 cannot reasonably be considered to be “arbitrarily-shaped electrodes” as claimed in the present invention.

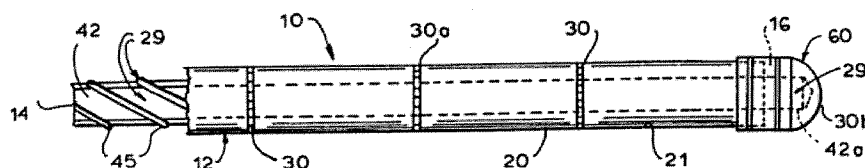
For at least the foregoing reasons, Winkler fails to teach each and every element of, and therefore does not anticipate claim 33. Claims 16, 17, 19, 21-23, 25-27, and 29-32 depend from claim 33 and are allowable for at least the same reasons.

Applicant further submits that claim 16 is allowable for an additional and independent reason. Claim 16 recites that “the arbitrarily-shaped electrode is formed by electro-depositing a conductive, biocompatible material within a depression formed on the catheter tip.” As discussed above, Winkler teaches that the electrode is formed by crimping about the catheter body rather than by electro-deposition. Nor does Winkler teach a depression into which a conductive, biocompatible material is deposited.

Claim 32 is also allowable for an additional and independent reason. Claim 32 recites that “the portion of the overmold of the catheter remaining adjacent the exposed portion of the at least one arbitrarily-shaped electrode provides a generally smooth finish to the catheter.” Even assuming *arguendo* that the Examiner’s characterization of Winkler’s wire 45 as the claimed “arbitrarily-shaped electrode” is proper (which Applicant disputes), when the wire 45 is exposed through windows 47 in hard layer 20, Winkler’s device lacks the claimed “generally smooth finish,” as illustrated in Fig. 4A of Winkler, reproduced below.



As discussed above, and as recognized by the Examiner (Office action, para. 11), it is not until crimped electrode 30—which is *not* “exposed through and completely surrounded by” overmold, and therefore is *not* the claimed “arbitrarily-shaped electrode”—is in place that Winkler’s device possesses “a generally smooth finish.” *Id.*, Fig. 1 (reproduced below).



Thus, at no stage in manufacture does Winkler meet the limitation of “at least one arbitrarily-shaped electrode overmolded by a portion of the catheter, at least a portion of the at least one arbitrarily-shaped electrode being exposed through and completely surrounded by the overmold of the catheter[,]” “wherein the portion of the overmold of the catheter remaining adjacent the exposed portion of the at least one arbitrarily-shaped electrode provides a generally smooth finish to the catheter.”

For at least the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 16, 17, 19, 21-23, 25-27, and 29-33 under 35 U.S.C. § 102(b).

### **Rejections Under 35 U.S.C. § 103**

The Examiner rejects claims 16, 20, and 28 under 35 U.S.C. § 103 as obvious over Winkler. The Examiner also rejects claim 24 under 35 U.S.C. § 103 as obvious over Winkler in view of United States patent no. 5,125,913 to Quackenbush (“Quackenbush”). Applicant respectfully disagrees.

Though the prior art references need not teach or suggest each and every limitation of a claim for that claim to be obvious, Applicant contends that the differences between the rejected claims and the references cited are sufficiently great so as to render the claimed invention non-obvious to one of ordinary skill in the art at the time the invention was made. Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57527-28 (Oct. 10, 2007) (“[T]he focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and *on what such a person would have reasonably expected to have been able to do in view of that knowledge.*”) (emphasis added). In particular, as discussed at length above, Applicant contends that the cited references do not teach “at least a portion of the at least one arbitrarily-shaped electrode being exposed through and completely surrounded by the overmold of the catheter[,]” and thus one of ordinary skill in the art would not have learned the claimed invention from the asserted references.

Claims 16, 20, 24, and 28 depend from claim 33. The shortcomings of Winkler with respect to claim 33 have been discussed at length above. These shortcomings are not addressed through the addition of Quackenbush. Accordingly, Applicant submits that the claimed invention is substantially different from, and therefore non-obvious over, the asserted references. Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

**CONCLUSION**

In view of the foregoing remarks, Applicant respectfully submits that the application is in condition for allowance, and requests that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

No extension of time is believed necessary for this paper to be considered timely. Should an extension of time be deemed necessary, Applicant hereby petitions therefor under 37 C.F.R. § 1.136.

Authorization is hereby granted to charge any fees due with the filing of this document, including any fees for any extensions of time deemed necessary, to Deposit Account No. 50-1129 with reference to Attorney Docket No. 0B-045000US/82410-0067.

Respectfully submitted,

**WILEY REIN LLP**

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